Cardinal Health

3651 Birchwood Drive,

Waukegan,

Illinois,

USA 60085

01st May 2024

Notified Body Confirmation Letter

Reference: EU2023-607/ID 787221 V1

To whom it may concern,

Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices

This letter confirms that, **BSI Group The Netherlands B.V.**, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number **2797** on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer:

Cardinal Health

3651 Birchwood Drive,

Waukegan,

Illinois,

USA 60085

SRN Number: US-MF-000006765

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables below. Table 1 identifies the devices for which an MDR application has been received, written agreement concluded and for which the NB is also responsible for appropriate surveillance of the

corresponding devices under the applicable Directive. Table 2 identifies the devices for which an MDR application has been received and a written agreement concluded, but the NB has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

In the case of devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR respectively, by the 20 Mar 2023 for the relevant devices.

The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120.3c of MDR (as amended by (EU) 2023/607), are shown below:

- 26 May 2026 for Class III custom-made implantable devices
- 31 December 2027 for Class III devices and Class IIb implantable devices excluding Well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)
- 31 December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function
- 31 December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

On behalf of BSI Group The Netherlands B.V.,

Graeme Tunbridge
Senior Vice President, Medical Devices

Table 1: Devices covered by this letter and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Protexis PI Sterile Surgical Gloves with Hydrogel Coating	Class IIa – Non implantable	Not Applicable	MDD CE 553828 26/05/2024 NB 2797
Protexis Latex Sterile Surgical Gloves with Neu-Thera Coating	Class IIa – Non implantable	Not Applicable	MDD CE 553828 26/05/2024 NB 2797
Protexis Neoprene Sterile Surgical Gloves	Class IIa – Non implantable	Not Applicable	MDD CE 553828 26/05/2024 NB 2797
Protexis PI Sterile Surgical Gloves	Class IIa – Non implantable	Not Applicable	MDD CE 553828 26/05/2024 NB 2797
Protexis Latex Sterile Surgical Gloves with Nitrile Coating	Class IIa – Non implantable	Not Applicable	MDD CE 553828 26/05/2024 NB 2797
Protexis Latex Sterile Surgical Gloves with Hydrogel Coating	Class IIa – Non implantable	Not Applicable	MDD CE 553828 26/05/2024 NB 2797
Protexis PI Sterile Surgical Gloves with Neu-Thera Coating	Class IIa – Non implantable	Not Applicable	MDD CE 553828 26/05/2024 NB 2797
Yankauer Suction Handles	Class IIa – Non implantable	Not Applicable	MDD CE 554050 26/05/2024 NB 2797

Table 2: Devices covered by this letter and for which the NB is <u>NOT</u> responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Excilon™ AMD Antimicrobial I.V. Drain Sponges, 0.2% Polyhexamethylene Biguanide HCI (PHMB)	Class III/IIb (under classification dispute)	Not Applicable	*MDD G1 056759 0013 Rev. 00 NB 0123* *MDD G1 074735 0083 Rev. 00 NB 0123*
Kerlix™ AMD Antimicrobial Bandage Roll, 6 Ply, 0.2% Polyhexamethylene Biguanide HCI (PHMB)	Class III/IIb (under classification dispute)	Not Applicable	*MDD G1 056759 0013 Rev. 00 NB 0123* *MDD G1 074735 0083 Rev. 00 NB 0123*
Telfa™ AMD Antimicrobial Non-adherent Pad, 0.2% Polyhexamethylene Biguanide HCI (PHMB)	Class III/IIb (under classification dispute)	Not Applicable	*MDD G1 056759 0013 Rev. 00 NB 0123* *MDD G1 074735 0083 Rev. 00 NB 0123*
Kendall™ AMD Antimicrobial Foam Dressing, 0.5% Polyhexamethylene Biguanide HCI (PHMB)	Class III/IIb (under classification dispute)	Not Applicable	*MDD G1 056759 0013 Rev. 00 NB 0123* *MDD G1 074735 0083 Rev. 00 NB 0123*
Kendall™ AMD Antimicrobial Fenestrated Foam Disc Dressing, 0.5% Polyhexamethylene Biguanide HCI (PHMB)	Class III/IIb (under classification dispute)	Not Applicable	*MDD G1 056759 0013 Rev. 00 NB 0123* *MDD G1 074735 0083 Rev. 00 NB 0123*
Kendall™ AMD Antimicrobial Foam Border Dressing, 0.5% Polyhexamethylene Biguanide HCI (PHMB)	Class III/IIb (under classification dispute)	Not Applicable	*MDD G1 056759 0013 Rev. 00 NB 0123* *MDD G1 074735 0083 Rev. 00 NB 0123*
Kendall™ AMD Antimicrobial Fenestrated Foam Dressing with Top Sheet, 0.5% Polyhexamethylene Biguanide HCI (PHMB)	Class III/IIb (under classification dispute)	Not Applicable	*MDD G1 056759 0013 Rev. 00 NB 0123* *MDD G1 074735 0083 Rev. 00 NB 0123*
Kendall™ AMD Antimicrobial Foam Dressing with Top Sheet, 0.5% Polyhexamethylene Biguanide HCI (PHMB)	Class III/IIb (under classification dispute)	Not Applicable	*MDD G1 056759 0013 Rev. 00 NB 0123* *MDD G1 074735 0083 Rev. 00 NB 0123*
Kendall™ AMD Antimicrobial Foam Dressing with Top Sheet, 0.5% Polyhexamethylene Biguanide HCI (PHMB)	Class III/IIb (under classification dispute)	Not Applicable	*MDD G1 056759 0013 Rev. 00 NB 0123* *MDD G1 074735 0083 Rev. 00 NB 0123*
Kangaroo Feeding Set & 3-in-1 Adaptor	Class IIa – Non implantable	Not Applicable	*MDD G1 056759 0013 Rev. 00 NB 0123* *MDD G1 074735 0083 Rev. 00 NB 0123*

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Kangaroo™ Joey Pump Set	Class IIa – Non implantable	Not Applicable	*MDD G1 056759 0013 Rev. 00 NB 0123* *MDD G1 074735 0083 Rev. 00 NB 0123*
Kangaroo ePump Enteral Feeding Sets	Class IIa – Non implantable	Not Applicable	*MDD G1 056759 0013 Rev. 00 NB 0123* *MDD G1 074735 0083 Rev. 00 NB 0123*
Kangaroo Non-sterile ePump Enteral Feeding Sets	Class IIa – Non implantable	Not Applicable	*MDD G1 056759 0013 Rev. 00 NB 0123* *MDD G1 074735 0083 Rev. 00 NB 0123*
Epump and Joey Burette Recertification Set	Class IIa – Non implantable	Not Applicable	*MDD G1 056759 0013 Rev. 00 NB 0123* *MDD G1 074735 0083 Rev. 00 NB 0123*
Kendall™ Calcium Alginate Dressing	Class IIb – non implantable	Not Applicable	*MDD G1 056759 0013 Rev. 00 NB 0123* *MDD G1 074735 0083 Rev. 00 NB 0123*
Argyle Surgical Suction Devices - Yankauer Suction Set	Class IIa – Non implantable	Not Applicable	*MDD G1 056759 0013 Rev. 00 NB 0123* *MDD G1 074735 0083 Rev. 00 NB 0123*
Argyle Surgical Suction Devices - Yankauer Selec-Trol – Rigid	Class IIa – Non implantable	Not Applicable	*MDD G1 056759 0013 Rev. 00 NB 0123* *MDD G1 074735 0083 Rev. 00 NB 0123*
Argyle Surgical Suction Devices - Yankauer Selec-Trol – Flexible	Class IIa – Non implantable	Not Applicable	*MDD G1 056759 0013 Rev. 00 NB 0123* *MDD G1 074735 0083 Rev. 00 NB 0123*
Argyle Surgical Suction Devices - Yankauer Rigid	Class IIa – Non implantable	Not Applicable	*MDD G1 056759 0013 Rev. 00 NB 0123* *MDD G1 074735 0083 Rev. 00 NB 0123*
Argyle Surgical Suction Devices - Yankauer Flexible - Yankauer Flexible Non-Sterile	Class IIa – Non implantable	Not Applicable	*MDD G1 056759 0013 Rev. 00 NB 0123* *MDD G1 074735 0083 Rev. 00 NB 0123*
Kangaroo™ Gastrostomy Feeding Tube with ENFit Y-Port	Class IIb	Not Applicable	*MDD G1 056759 0013 Rev. 00 NB 0123*

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
			MDD G1 074735 0083 Rev. 00 NB 0123
Magellan Hypodermic Safety Needle	Class IIa – Non implantable	Not Applicable	*MDD G1 056759 0013 Rev. 00 NB 0123* *MDD G1 074735 0083 Rev. 00 NB 0123*
Argyle™ Thoracic Catheter, Straight	Class IIa – Non implantable	Not Applicable	*MDD G1 056759 0013 Rev. 00 NB 0123* *MDD G1 074735 0083 Rev. 00 NB 0123*
Argyle™ Thoracic Catheter, Right Angle	Class IIa – Non implantable	Not Applicable	*MDD G1 056759 0013 Rev. 00 NB 0123* *MDD G1 074735 0083 Rev. 00 NB 0123*
Argyle™ Trocar Catheter, Sharp Tip	Class IIa – Non implantable	Not Applicable	*MDD G1 056759 0013 Rev. 00 NB 0123* *MDD G1 074735 0083 Rev. 00 NB 0123*
Xeroform™ Occlusive Gauze Patch 3% Bismuth Tribromophenate in Petrolatum Blend	Class III/IIb (under classification dispute)	Not Applicable	*MDD G1 056759 0013 Rev. 00 NB 0123* *MDD G1 074735 0083 Rev. 00 NB 0123*
Kendall™ Hydrophilic Foam Dressing	Class IIb - Non-Implantable - non-WET- non-Rule 12	Not Applicable	*MDD G1 056759 0013 Rev. 00 NB 0123* *MDD G1 074735 0083 Rev. 00 NB 0123*
Turkel™ Safety Thoracentesis and Paracentesis System	Class IIa – Non implantable	Not Applicable	*MDD G1 056759 0013 Rev. 00 NB 0123* *MDD G1 074735 0083 Rev. 00 NB 0123*
Magellan™ Insulin Safety Syringe , Permanent Needle	Class IIa – Non implantable	Not Applicable	*MDD G1 056759 0013 Rev. 00 NB 0123* *MDD G1 074735 0083 Rev. 00 NB 0123*
Magellan™ Tuberculin Safety Syringe, Permanent Needle	Class IIa – Non implantable	Not Applicable	*MDD G1 056759 0013 Rev. 00 NB 0123* *MDD G1 074735 0083 Rev. 00 NB 0123*
Medi-Trace Cadence Adult Mult-Function Defibrillation Electrodes Pre-Connect	Class IIb - Non-Implantable - non-WET- non-Rule 12	*Not Applicable*	*MDD G1 056759 0013 Rev. 00 NB 0123* *MDD G1 074735 0083 Rev. 00 NB 0123*

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Medi-Trace Cadence Pediatric Mult-Function Defibrillation Electrodes Radiotransparent	Class IIb - Non-Implantable - non-WET- non-Rule 12	*Not Applicable*	*MDD G1 056759 0013 Rev. 00 NB 0123* *MDD G1 074735 0083 Rev. 00 NB 0123*
Medi-Trace Cadence Adult Mult-Function Defibrillation Electrodes Radiotransparent	Class IIb - Non-Implantable - non-WET- non-Rule 12	*Not Applicable*	*MDD G1 056759 0013 Rev. 00 NB 0123* *MDD G1 074735 0083 Rev. 00 NB 0123*
Medi-Trace Cadence Adult Mult-Function Defibrillation Electrodes	Class IIb - Non-Implantable - non-WET- non-Rule 12	*Not Applicable*	*MDD G1 056759 0013 Rev. 00 NB 0123* *MDD G1 074735 0083 Rev. 00 NB 0123*
Argyle Replogle Suction Catheters	Class IIa - Non-Implantable	*Not Applicable*	*MDD G1 056759 0013 Rev. 00 NB 0123* *MDD G1 074735 0083 Rev. 00 NB 0123*
Kangaroo Joey Enteral Feeding Pumps	Class IIa - Non-Implantable	*Not Applicable*	*MDD G1 056759 0013 Rev. 00 NB 0123* *MDD G1 074735 0083 Rev. 00 NB 0123*
Kangaroo ePump Enteral Feeding Pumps	Class IIa - Non-Implantable	*Not Applicable*	*MDD G1 056759 0013 Rev. 00 NB 0123* *MDD G1 074735 0083 Rev. 00 NB 0123*
Filac Thermometers	Class Iia- Non- Implantable	*Not Applicable*	*MDD G1 056759 0013 Rev. 00 NB 0123* *MDD G1 074735 0083 Rev. 00 NB 0123*

Confirmation Letter Revision History

Date	Action
2024/02/26	Initial issue
2024/05/01	Revision to include additional products into table 2 and to include mirror CE certificate for devices covered in table 2